FEB 12 2004

K040066

510(K) SUMMARY FOR THE SIREMOBIL C 06

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

January 13, 2004

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Nealie Hartman
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787

2. Device Name and Classification:

Trade Name:	Siremobil C 06 (C06 is internal project name, final name assignment will be determined prior to FDA clearance)
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	90IZL

3. Substantial Equivalence:

The Siremobil C 06 is substantially equivalent to the following devices:

Predicate Device Name	*510(k) Number*	*Clearance Date*	*Comparable Properties*
Siemens Siremobil Compact	K963093	08/07/1996	• Hardware • Control Software • Intended use
Siemens Siremobil Iso-C	K973598	11/10/1997	• Hardware • Control Software • Intended use

4. Device Description:

The Siremobil C 06 is a mobile x-ray system which consists of a mobile C-arm configured with a high frequency generator, X-ray tube assembly, image intensifier, TV camera, film cassette attachment, laser target devices, electronics cabinet, a monitor trolley and digital image storage system which consists of the digital memory device, image monitor(s), and user interface. The system is equipped with a footswitch and a hand switch for radiation release in the five modes of operation: digital radiography, fluoroscopy, pulsed fluoroscopy, subtraction, and roadmapping.

5. Intended Use of the Device:

The Siremobil C06 is a mobile x-ray system intended for use in operating room, traumatology, endoscopy, intensive care station, pediatrics, ambulatory patient care and in veterinary medicine. The Siremobil 06 can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Cassette Exposures, Digital Subtraction, and Roadmapping, which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

6. Summary of Technological Characteristics of the Devices Compared to the Predicate:

The Siremobil C 06 is a modification to the Siremobil Compact. Mechanically the changes are minor in design and style. The X-ray generator, X-ray tube and Image Intensifier are identical with the currently cleared product.

The imaging chain reflects the current standard of 1024^2 image processing and display with flat screen monitors. It was originally cleared with a stationary X-ray system (Uroskop Access) and is in clinical operation since more than 2 years. An uninterruptable power supply provides additional safety to image and demographic data in the event of a power outage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2004

Ms. Nealie Hartman
Technical Specialist Regulatory
Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway J-15
MALVERN PA 19355

Re: K040066
Trade/Device Name: Siremobil CO6
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: January 13, 2004
Received: January 13, 2004

Dear Ms. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040066
Device Name: SIREMOBIL C06

Indications For Use:

The Siremobil C06 is a mobile x-ray system intended for use in operating room, traumatology, endoscopy, intensive care station, pediatrics, ambulatory patient care and in veterinary medicine. The Siremobil 06 can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Cassette Exposures, Digital Subtraction, and Roadmapping, which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040066